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EXAMINER	
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte THOMAS BECKERT, JENNIFER DRESSMAN, and MARKUS RUDOLPH

Appeal 2011-000963
Application 10/501,236
Technology Center 1600

Before ERIC GRIMES, JEFFREY N. FREDMAN, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a pharmaceutical formulation, which have been rejected for obviousness. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

The Specification states that "[o]ne problem with pharmaceutical formulations containing the active ingredient budesonide is the low solubility of the active ingredient" (Spec. 2: 33-35). The Specification

discloses a formulation containing an "inner layer . . . [that] comprises the active ingredient budesonide, bound in a polymeric binder with acidic groups" (*id.* at 5: 9-11). The Specification hypothesizes that "there is an interaction between polymeric binders with acidic groups and the budesonide which increase[s] the solubility of the budesonide. The exact molecular mechanism of the increase in solubility in this connection is unknown. It is merely assumed that the acidic groups are involved therein." (*Id.* at 6: 21-27.)

Claims 1, 2, 4-8, and 10-12 are on appeal. Claim 1 is representative and reads as follows:

Claim 1: A pharmaceutical formulation comprising

a) an inner layer with the active ingredient budesonide bound in a binder

b) an intermediate layer with a polymeric coating agent which is soluble in intestinal juice or extends release,

c) an outer envelope which is resistant to gastric juice or an outer layer with a coating agent which is resistant to gastric juice

where the layers may comprise further pharmaceutically acceptable excipients,

wherein the binder is a polymer or copolymer with acidic groups, and the formulation of the inner layer without intermediate and outer layer releases the bound active ingredient in the release test according to USP XXIII monograph <711> "Dissolution" with apparatus 2 (paddle) with 100 revolutions/min in phosphate buffer of pH 7.5 to the extent of more than 80% after 30 min.

The Examiner has rejected all of the claims on appeal under 35 U.S.C. § 103(a) as obvious based on Beckert[1] (Answer 4). The Examiner finds that Beckert discloses a pharmaceutical product comprising a core containing a

[1] Beckert et al., US 6,632,454 B2, issued Oct. 14, 2003.

pharmaceutically active substance, which can be budesonide, and the inner and outer layers required by claim 1 (Answer 4). The Examiner finds that the "dosage form includes a binder such as collidon [sic] 25 as well as an internal coat of Eudragit RS and RL and an external enteric coating of Eudragit FS" and therefore the claimed invention would have been obvious to a person of ordinary skill in the art (*id.*).

Appellants argue that the Examiner has not shown prima facie obviousness because, among other things, "(1) there is no teaching or reasonable suggestion in Becker[t] '454 to employ any 'polymer or copolymer with acidic groups' as the binder for budesonide or any other active agent in its core; [and] (2) Becker[t] does not prima facie suggest using a binder with acidic groups for budesonide in the core" (Appeal Br. 15).

We agree with Appellants that the Examiner has not persuasively shown that Beckert would have made obvious a formulation comprising "an inner layer with the active ingredient budesonide bound in a binder . . . wherein the binder is a polymer or copolymer with acidic groups," as required by claim 1.

Beckert discloses a multilayer drug form that includes a "core with an active pharmaceutical ingredient," an inner coating, and an outer coating (Beckert, col. 1, l. 66 to col. 2, l. 8). Beckert discloses that "[b]eside the active ingredient, the cores may contain further pharmaceutical excipients: binders such as lactose, cellulose and derivatives thereof, polyvinyl-pyrrolidone (PVP)," and other standard excipients such as humectants and lubricants (*id.* at col. 3, ll. 20-23).

The Examiner acknowledges that PVP is not a polymer with acidic groups (Answer 6-7) but argues that "Beckert clearly teaches a polymer or copolymer with acidic groups and is not limited to the use of [PVP]" (*id.* at 7). However, the disclosures that the Examiner cites in support of this statement relate to the inner and outer coatings of Beckert's multilayer drug form, not to the drug-containing core. The Examiner has not pointed to any disclosure in Beckert of a core containing an active agent and a polymer with acidic groups, nor has the Examiner provided evidence or sound reasoning to support a conclusion that it would have been obvious to include such a polymer in the core of Beckert's drug form.

We therefore reverse the rejection of claims 1, 2, 4-8, and 10-12 under 35 U.S.C. § 103(a) based on Beckert.

REVERSED

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